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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,634	12/05/2001	Anthony E. Bolton	355908-2500	1971

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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,634	BOLTON ET AL.	
	Examiner	Art Unit	
	Michail A. Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/01/06 has been entered.

Claims 19-32 are pending.

2. *Claims 19-32 drawn to a method of decreasing expression of one ore more inflammatory cytokines and a method of treatment or prophylaxis of chronic fatigue syndrome in mammalian each comprising administering stressed mammalian blood cells wherein stressor is both oxidative conditions and ultraviolet radiation are under consideration in the instant application.*

The following new ground of rejections are necessitated by the amendment filed on 05/01/06.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 19-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection**.

"selecting a patient with an excess of inflammatory cytokines, selected from the group of IFN-γ and IL-6" claimed in claims 19 and 26 represent(s) a departure from the specification and the claims as originally filed. The passages pointed by the applicant do not provide a clear support for " selecting a patient with an excess of inflammatory cytokines, selected from the group of IFN-γ and IL-6 " claimed in claims 19 and 26

The specification and the claims as originally field only support a method for treating or prophylaxis of an inflammatory disease conditions in a patient mediated by excess inflammatory cytokine, said cytokine being selected from the group consisting of IFN-γ and IL-6.

5. Claims 26-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of decreasing the expression of one or more of the inflammatory cytokines IFN-γ and IL-6 from cells in mammalian patients comprising administering to the patient an effective amount of stressed mammalian blood cells wherein said blood cells have been extracorporeally subjected to both oxidative conditions and UV radiation does not reasonably provide **enablement** for a method for treatment or prophylaxis chronic fatigue syndrome in a patient comprising administering to the patient an effective amount of stressed mammalian blood cells wherein said blood cells have been extracorporeally subjected to both oxidative conditions and UV radiation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim for the same reasons set forth in the previous Office Actions, mailed on 02/26/04 and 10/11/05.

It is the Examiner position that Specification does not reasonably provide enablement for a method for treatment or prophylaxis of any inflammatory disease, including chronic fatigue syndrome in a patient comprising administering to the patient an effective amount of stressed mammalian blood cells wherein said blood cells have been extracorporeally subjected to both oxidative conditions and UV radiation.

Moreover, in the interview with Applicant's representatives Jerald Swiss and Bill Chan on 05/26/05, the Examiner acknowledge that specification only enable for a process of decreasing the expression of one or more of the inflammatory cytokines IFN-γ and IL-6 from cells in mammalian patients comprising administering to the patient an effective amount of stressed mammalian blood cells wherein said blood cells have been extracorporeally subjected to both oxidative conditions and UV radiation. Applicant previously amend the base claim 12 to recite " A method of decreasing the level of IL-6 in a patient" in the response filed on 10/11/05.

As has been stated in the previous Office Actions, since there is no animal model studies and data in the specification to show the effectively of treatment or prophylaxis of chronic fatigue syndrome in a patient comprising administering to the patient an effective amount of stressed mammalian blood cells wherein said blood cells have been extracorporeally subjected to both oxidative conditions and UV radiation it is unpredictable how to correlate a contact hypersensitivity (CHS) test on Balb/c mice and the decrease in the expression levels for cytokines IFN-γ and IL-6 in the lymph tissue of the treated animals with claimed *in vivo* use.

Applicant himself acknowledge that etiology of CFS remains unknown and it is well known in the art that excessive sensitivity to IL-6 are almost certainly not the only factor controlling CFS (see page 9, lines 20-25 in particular). In other words Applicant acknowledge that treatment and prophylaxis of CSF is subject to a number of factors which enter the picture beyond simply reduction in the levels of IL-6 by administering stressed blood cells. Moreover, Cannon et al., (J of Clinical Immunology, 1999, Vol.19, pages 414-421) teach that there are still some discrepancy in correlation of the levels of IL-6 in serum of CFS patients due to individual variability. Cannon et al., further teach that though abnormalities in cytokine secretion have been detected in CDF patient, it is still an open question whether they contribute substantially to the expressions of CFS (see page 420 in particular).

Since the method of treatment or prophylaxis of chronic fatigue syndrome in a patient, by administering an effective amount of stressed mammalian blood cells can be species- and model-dependent (see Van Noort et al. International Review of Cytology, 1998, v.178, pages 127-204, Table III in particular) , it is not clear that reliance on the contact hypersensitivity (CHS) test on Balb/c mice and the decrease in the expression levels for cytokines IFN-γ and IL-6 in the lymph tissue of the treated animals accurately reflects the relative mammal and human efficacy of the claimed therapeutic strategy. The specification does not teach how to extrapolate data obtained from the above discussed studies to the development of effective *in vivo* mammalian including human therapeutic treatment, commensurate in scope with the claimed invention. Therefore, it is not clear that the skilled artisan could predict the efficacy of a method of treatment or prophylaxis of chronic fatigue syndrome in a patient, by administering an effective amount of stressed mammalian blood cells. Thus in the absence of working examples or detailed guidance in the specification, the intended uses of any pharmaceutical composition comprising stressed mammalian blood cells to treatment or prophylaxis of CFS are fraught with uncertainties.

Also the issue is that the nature of the invention is such that it would require the administration of blood cells that have been extracorporeally subjected to both oxidative conditions and UV radiation that would prevent a mammalian subject from having inflammatory disease. The burden of enabling the prevention of a disease (i. e. the need for additional testing) would be greater than that of enabling a treatment due to the need to screen those humans susceptible to such diseases and the difficulty of proof that the administration of stressed blood cells was the agent that acted to prevent the condition. Further, the specification does not provide guidance as to how one skilled in the art would go about screening those patients susceptible to any inflammatory disease, including chronic fatigue syndrome within the scope of the presently claimed invention. Nor is guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed compounds in preventing these disease states. Accordingly, undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed invention.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed method of treatment or prophylaxis of any inflammatory disease, including chronic fatigue syndrome comprising administering an effective amount of a therapeutically effective amount of of stressed mammalian blood cells in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 19-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/07463 or U.S. Patent No. 5,980,954 or WO00/06703 each in view of Gupta et al., (International J. of Molecular Medicine, 1999, Vol.3, pages 209-213).

WO ' 703 teaches a method of treating GVHD in a mammalian patient comprises administering to the patient stressed mammalian blood cells (see the entire document Abstract in particular . The WO '703 teaches that stress blood cells have been extracting from the patient an aliquot of blood of volume, contacting the aliquot of blood, extracorporeally subject to at both oxidative conditions, ultraviolet radiation and heat stress simultaneously. (see overlapping pages 5-6 and 7 in particular). The WO '703 teaches that oxidative environment, such as a mixture of ozone, wherein an ozone content from about 1 to about 100 μg/ml and oxygen bubbled through the blood aliquot, from about 0.5 to 60 min (pages 7 and 9 , in particular). The WO '703 teaches that the temperature stressor is in a range from about 40 to about 55° C (see pages 8 and 11 in particular). The WO '703 teaches that UV stessor is UV-c radiation (see page 8 in particular). Wherein the patient is human and the aliquot of modified mammalian blood is the patient's own blood , of volume from about 0.1- 500 ml (page 7, in particular).

The WO ' 436 teaches a method of treating an inflammatory disease including inflammatory bowel disease and rheumatoid arthritis in a mammalian patient comprises administering to the patient stressed mammalian blood cells (see the entire document, pages 1, 17, and 23 in

particular) . The WO ' 436 teaches that stress blood cells have been extracting from the patient an aliquot of blood of volume, contacting the aliquot of blood, extracorporeally subject to at both oxidative conditions, ultraviolet radiation and heat stress simultaneously. (see overlapping pages 13-14 and 16-17 in particular). The WO ' 436 teaches that oxidative environment, such as a mixture of ozone, wherein an ozone content from about 1.0 to about 100 μg/ml and oxygen bubbled through the blood aliquot, from about 0.5 to 60 min (pages 14-15, in particular). The WO ' 436 teaches that the temperature stressor is in a range from about 40 to about 55° C (see page 14 in particular). The WO ' 436 teaches that UV stessor is UV-c radiation (see page 15 in particular). Wherein the patient is human (page 8, paragraph 3 in particular), and the aliquot of modified mammalian blood is the patient's own blood (page 12, paragraph 4 in particular), of volume from about 0.01-400 ml (pages 8, 13, in particular).

The US Patent '954 teaches a method of treating an inflammatory disease including inflammatory bowel disease and rheumatoid arthritis in a mammalian patient comprises administering to the patient stressed mammalian blood cells (see the entire document, column 1, and overlapping columns 7 –8 in particular). The US Patent '954 teaches that stress blood cells have been extracting from the patient an aliquot of blood of volume, contacting the aliquot of blood, extracorporeally subject to at both oxidative conditions, ultraviolet radiation and heat stress simultaneously. (see column 6, in particular). The US Patent '954 teaches that oxidative environment, such as a mixture of ozone, wherein an ozone content from about 0.5 to about 100 μg/ml and oxygen bubbled through the blood aliquot, from about 0.5 to 60 min (see overlapping columns 7-8 and Claim 5 in particular). US Patent' 954 teaches that the temperature stressor is in a range from about 37 to about 55° C (see column 7 and claim 4 in particular). The US Patent '954 teaches that UV stessor is UV-c radiation (see column 8 in particular). Wherein the patient is human, and the aliquot of modified mammalian blood is the patient's own blood of volume from about 0.01-400 ml (column 9 and claim 2 in particular).

WO 98/07463 , U.S. Patent No. 5,980,954 or WO00/06703 do not explicitly teach a method of decreasing expression of one or more inflammatory cytokines selecting from the group of IFN- γ and IL-6 , as recited in claims 19-25 or treating of prophylaxis of chronic fatigue syndrome (CFS) as recited in claims 26-32, each comprising selecting a patient with an excess of inflammatory cytokines selecting from the group of IFN- γ and IL-6 and administering stressed mammalian blood cells .

Gupta et al., teach that overproduction of IL-6 contributed to many inflammatory diseases including patient with chronic fatigue syndrome (CFS). (see entire document, Abstract in particular). Gupta et al., teach the existence of correlation between increasing in the levels of IL-6 and clinical manifestation of CFS (see page 212 in particular). Gupta et al., teach that IL-6 may play a role in the symptomatology during the natural course of CFS.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Gupta et al., to those of WO 98/07463 or U.S. Patent No. 5,980,954 or WO00/06703 to obtain a claimed method of decreasing expression of one or more inflammatory cytokines selecting from the group of IFN- γ and IL-6 , as recited in claims 19-25 or treating of prophylaxis of chronic fatigue syndrome (CFS) as recited in claims 26-32, each comprising selecting a patient with an excess of inflammatory cytokines selecting from the group of IFN- γ and IL-6 and administering stressed mammalian blood cells .

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because overproduction of IL-6 contributed to many inflammatory diseases including patient with chronic fatigue syndrome as taught by Gupta et al ., and can be treated by the method for treatment of an inflammatory diseases taught by WO 98/07463 , U.S. Patent No. 5,980,954 or WO00/06703. It is clear that both the prior art references and applicant administered the same composition, i.e. stressed mammalian blood cells to the same patient to achieve the same results, i.e. treating inflammatory disease. Moreover, since the reference method using the same treatment as claimed , it would be obvious that administered stressed mammalian blood cells would result in decreasing the expression of one or more inflammatory cytokines . When the prior art method is the same as a method described in the specification, it can be assumed the method will obviously perform the claimed process absent a showing of unobvious property. Moreover, since Gupta et al., teach that overproduction of one of inflammatory cytokines , i.e. IL-6 contributed to many inflammatory diseases, including CFS it would be obvious to person of ordinary skill in the art to select a patient with excess of inflammatory cytokines IL-6 prior of treating an inflammatory disease, including CFS.

Claim 15 is included because the claimed ozone content from about 0.1 to about 100 μg/ml is an obvious variation of reference ranges of 1.0-100μg/ml, taught by WO'703 and WO'436 and 05-100 μg/ml taught by US Patent '954 . Therefore, the claimed invention is an obvious variation of the reference teachings, absent a showing of unobvious differences. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 19-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5,980,954 in view of Gupta et al., (International J. of Molecular Medicine, 1999, Vol.3, pages 209-213).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-12 of U.S. Patent No. 5,980,954 recites a method treating an inflammatory disease including inflammatory bowel disease and rheumatoid arthritis in a mammalian patient comprises administering to the patient stressed mammalian blood cells patient, comprising administering to said patient an effective amount of stressed blood cells, wherein said blood cells have been subjecting to stress comprising oxidative condition and an ultraviolet stressor, or wherein the ozone content in the gas mixture is from 0.5 –100 μg/ml; or wherein ultraviolet stressor is UV-C; or wherein the temperature range from about 37 to about 55^0 C , or wherein the stressed blood cell comprise a volume of the whole blood from about 0.1 to 400ml.

Claims 1-12 of U.S. Patent No. 5,980,954 do not explicitly teach a method of decreasing expression of one or more inflammatory cytokines selecting from the group of IFN- γ and IL-6 , as recited in claims 19-25 or treating of prophylaxis of chronic fatigue syndrome (CFS) as recited in claims 26-32, each comprising selecting a patient with an excess of inflammatory cytokines selecting from the group of IFN- γ and IL-6 and administering stressed mammalian blood cells .

Gupta et al., teach that overproduction of IL-6 contributed to many inflammatory diseases including patient with chronic fatigue syndrome (CFS). (see entire document, Abstract in particular). Gupta et al., teach the existence of correlation between increasing in the levels of IL-6 and clinical manifestation of CFS (see page 212 in particular). Gupta et al., teach that IL-6 may play a role in the symptomatology during the natural course of CFS.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Gupta et al., to those of Claims 1-12 of U.S. Patent No. 5,980,954 to obtain a claimed method of decreasing expression of one or more inflammatory cytokines selecting from the group of IFN- γ and IL-6 , as recited in claims 19-25 or treating of prophylaxis of chronic fatigue syndrome (CFS) as recited in claims 26-32, each comprising selecting a patient with an excess of inflammatory cytokines selecting from the group of IFN- γ and IL-6 and administering stressed mammalian blood cells .

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because overproduction of IL-6 contributed to many inflammatory diseases including patient with chronic fatigue syndrome as taught by Gupta et al ., and can be treated by the method recited in claims 1-12 of U.S. Patent No. 5,980,954. It is clear that both the prior art references and applicant administered the same composition, i.e. stressed mammalian blood cells to the same patient to achieve the same results, i.e. treating inflammatory disease. Moreover, since the reference method using the same treatment as claimed , it would be obvious that administered stressed mammalian blood cells would result in decreasing the expression of one or more inflammatory cytokines . When the prior art method is the same as a method described in the specification, it can be assumed the method will obviously perform the claimed process absent a showing of unobvious property. Moreover, since Gupta et al., teach that overproduction of one of inflammatory cytokines , i.e. IL-6 contributed to many inflammatory diseases, including CFS it would be obvious to person of ordinary skill in the art to select a patient with excess of inflammatory cytokines IL-6 prior of treating an inflammatory disease, including CFS.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAIL BELYAVSKYI, PH.D.
PATENT EXAMINER

7/21/06